NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Non-Sterile Compounding Inspection: Instruction Sheet and Form

(Revised 1/2022)

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.

To minimize any disruption to your facility during the inspection process please have the following available:

1. Completed Non-Sterile Compounding Inspection form along with prior year inspection form
2. Most recent certification report for any powder hoods located at the pharmacy and documentation of corrective action taken by facility for any failures documented on the certification report
3. Prior 12 months of competency documentation for compounding personnel
4. Examples of compounding worksheets
5. Examples of master formulations
6. SOP's relevant to the non-sterile compounding process
7. Potency testing results (if utilizing BUD in excess of USP 795 guidelines)

Pharmacy Information	
Date Completed:	
Pharmacy Name:	
Pharmacy License #:	
Pharmacy Address:	
Pharmacy Telephone #:	
Pharmacy Fax #:	
Pharmacy Email:	
Managing Pharmacist Name:	
Managing Pharmacist start date:	

List of compounding personnel approved to compound non-sterile products (Make copies of this page if additional space is needed)			
#	Name (First, Last)	License Number	Position
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Non-Sterile Compounding Categories				
Citation	**Question**	**Yes**	**No**	**NA**
USP 795	Does the pharmacy compound simple non-sterile products? Simple non-sterile products are defined as making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedures and equipment, and stability data for that formulation with appropriate BUD's; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.			
	Does the pharmacy compound moderate non-sterile products? Moderate non-sterile products are defined as making a preparation that requires special calculations or procedures to determine quantities of components per preparation or per individualized dosage unit; or making a preparation for which stability data for that specific formulation is not available.			
	Does the pharmacy compound complex non-sterile products? Complex non-sterile products are defined as making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.			

Standard Operating Procedures				
Citation	**Question**	**Yes**	**No**	**NA**
	The pharmacy has a written standard operating procedure manual with detailed instructions that describes how, when, and by whom all relevant Nevada Revised Statutes and Administrative Codes are to be met relating to the non-sterile compounding process?			
NAC 639.707 NAC 639.708	The patient is properly counseled about the compounded preparation at the time of dispensing?			
USP 795	The date of receipt of bulk product is noted on the container?			
	Packages of ingredients that lack a supplier expiration date are assigned a conservative expiration date not to exceed 3 years based on the nature of the component?			
	If a product is transferred from the original manufacturer's container, the container is identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container.			
NAC 639.757 USP 795	Non-sterile ingredients, substance, and excipients are official USP or NF grade and COA are available for review?			
NAC 639.757	If non USP or NF food, cosmetics, or other substances are used, the active ingredients are from an approved FDA manufacturer or distributor and are accompanied by a COA?			
NAC 639.757	If neither of the above 2 conditions are met, the active ingredients have been certified by the compounding pharmacy though an independent analysis by a laboratory to the satisfaction of the board?			
FDA	The pharmacy does not perform anticipatory compounding of more than a 30-day supply based on the pharmacy's prior sales?			
NAC 639.757	The pharmacy does not sell or otherwise provide a compounded drug to a retail pharmacy or a practitioner, except to a practitioner who will be administering the drug to a patient or to a practitioner or another pharmacy if the compounded drug is a highly concentrated drug product that is not commercially available or needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy?			

Policies and Procedures				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67015 NAC 639.67035 USP 795	The pharmacy maintains policies and procedures for compounding non-sterile compounded products?			
	The policies and procedures include but are not limited to the following:			
	Each final product has the identity, strength, quality, and purity which the compounded drug product it purported or represented to have?			
	The components used to compound each non-sterile compounded drug product is recorded on the prescription or in the computer record?			
	The amount of each component used to compound each non-sterile product?			
	The order of each step in the process of compounding each non-sterile product?			
	Beyond use dating?			
	Chemical and physical stability?			
	Cleaning and disinfecting?			
	Component quality evaluation?			
	Compounding methods?			
	Dispensing?			
	Documentation?			
	Environmental quality and maintenance?			
	Equipment maintenance, calibration, and operation?			
	Formulation development?			
	Labeling?			
	Material and final compounded preparation handling and storage?			
	Measuring and weighing?			
	Packaging and repackaging?			
	Patient monitoring, complaints, and adverse event reporting?			
	Patient or caregiver education and training?			
	Personnel cleanliness and garb?			
	Purchasing?			
	Quality assurance and continuous quality monitoring?			
	Shipping?			
	Testing?			
	Training and retraining?			

Control Procedures				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67035 USP 795	Control procedures for monitoring each final non-sterile product and for validating the compounding process are in place.			
	The control procedures include, without limitation the following:			
	Only one preparation is compounded at one time in a specific workplace?			
	Any variation of more than plus or minus 10% in the weight of capsules, tablets, or any other solid form of a dosage unit?			
	The adequacy of mixing to ensure uniformity and homogeneity of each compounded product?			
	If applicable, the clarity, completeness, and pH of the compounded product?			
	If applicable, the even distribution of coloring agents?			
	If there is any variation of more than plus or minus 10% in the actual yield of the compounded product as compared to the theoretical yield of the compounded product?			
	If the final compounded product is a capsule, that the capsule is properly locked?			

	If the final compounded product is a tablet or other solid form of dosage, the final compounded product is of a uniform size and is intact?			
	If the final compounded product is a suppository, the suppository is properly sealed?			
	If the final compounded product is an oral liquid, to the extent possible, the liquid is palatable to the patient?			
	If the final compounded product is a suspension, the visible suspended particles are of uniform size and are readily dispersed upon shaking?			
	If the final compounded product is a topical compounded product, the final product is smooth and not gritty and has a uniform viscosity unless grittiness is required for a particular therapeutic purpose?			

Compounding Personnel Training and Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67013	Documentation is on file for each person who compounds non-sterile products that they are adequately skilled, educated, instructed, and trained to correctly perform non-sterile compounding?			
NAC 639.67013 NAC 639 .67037	All pharmacists, interns, technicians, and technicians in training are trained in the following:			
	Perform proper hand cleansing before and after compounding?			
	Perform disinfection of compounding surfaces?			
	Select and appropriately don protective garb?			
	Identify, weigh, and measure ingredients?			
	Label and quality inspect non-sterile products?			
	Treatment of employees of the pharmacy with regard to contact and inhalation exposure?			
	Procedures for containment, cleaning, and disposal with regard to breaks and spills?			
	Compounding, handling, cleaning, and special techniques?			
	All pharmacists, interns, technicians, and technicians in training who compound hazardous drugs (HD) have been trained in:			
	The storage of HD?			
	The handling of HD?			
	The safety procedures of HD?			
	The disposal of HD?			
	Procedures for containment, cleaning, and disposal with regard to breaks and spills?			
	Treatment of employees with regard to exposure by contact and inhalation?			
	Safe manipulation practices that minimize exposure to the HD and protects the employees from any overt exposure?			
	Protection of personnel and compounding environment from contamination by HD?			
	All compounding personnel that compound a HD receives initial training and annual training thereafter?			
	The pharmacy keeps a record of any training given related to dangerous drug or HD compounding?			

Equipment				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.6701 NAC 639.67033 NAC 639.67019	Records are available for review for all equipment used in compounding. The records include, but are not limited to equipment set-up, calibration, filter changes, any periodic testing required, and cleaning of the equipment?			
	Are cleaning/calibration/maintenance daily logs available?			
	Are required certifications are on file for all equipment that require certification?			
	Are records of all equipment calibrations, maintenance, and testing are kept for the life of the equipment?			

Master Compounding Formulation Record				
Citation	**Question**	**Yes**	**No**	**NA**
USP 795 NAC 639.67019	All records are maintained for a minimum of 2 years.			
	A master formulation record is available for review.			
	A master formulation record is followed each time the specific formulation is compounded.			
	The master formulation record contains, but is not limited to the following:			
	Official or assigned name, strength, and dosage form of the preparation?			
	All necessary calculations including calculations needed to determine and verify quantities of components and doses of API's?			
	Description of all ingredients and quantities?			
	Compatibility and stability information, including references when available?			
	Equipment needed to prepare the preparation when appropriate?			
	Mixing instructions that should include order of missing, mixing temperature or other environmental controls, duration of mixing, and other factors pertinent to the replication of the preparation as compounded?			
	Container to use in dispensing and packaging requirements?			
	Labeling information including the name and quantity or concentration of each ingredient?			
	Description of final preparation?			
	Storage requirements?			
	Quality control procedures and expected results?			
	A copy of all documentation validating any extended beyond use date is readily available for review?			

Compounding Record				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.6701 NAC 639.6702	A detailed compounding record is maintained on the prescription or in the computer for each compounded preparation.			
NAC 639.67019 USP 795	The detailed compounding record maintained on each compounded preparation includes, but limited to, the following:			
	Official or assigned name, strength, and dosage of the preparation?			
	Master formulation record reference for the preparation?			
	Sources, lot numbers, and expiration dates of all components in the formulation?			
	Total quantity of dosage units compounded?			
	The order of each step in the compounding of each non-sterile product, if applicable?			
	The name and initials of the person(s) who prepared the preparation?			
	The name and initial of the person(s) who performed the quality control procedures?			
	The name initial of the pharmacist who approved the preparation?			
	The date of the compounding?			
	The assigned internal identification (lot number) or Rx number?			
	Description of the final preparation?			
	The beyond use date?			
	Results of the quality control procedures (e.g. weight range of the filled capsules)?			
	Documentation of any quality control issues, and any adverse reactions or preparation problems reported by the patient if applicable?			
	Any deviation from the master formulation record is documented?			
	A duplicate label as described in the master formulation record is attached?			

Non-Sterile Compounded Drug Labeling				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.6703	Non-sterile compounded product labels include, without limitation any amount of non-sterile compounded drug product in excess of the amount required by the prescription or chart order and any non-sterile compounded drug that is compounded in bulk. Each label at a minimum must contain the following:			
	The internal control number assigned to the compounded product?			
	The beyond use date of the compounded product?			
	The concentration of each active ingredient in the final compounded product?			
	Common name of final product or the name of each active ingredient?			
	Storage conditions?			

Beyond Use Dating				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.6703	A pharmacy may use a beyond use date later than the dates listed below if the pharmacy can prove by potency testing or published data that the non-sterile compounded product is safe and effective using the extended beyond use date. If multiple strengths of a formula are compounded, documentation to support each formulation must be available.			
	Does the pharmacy utilize beyond use dates in excess of USP-795 guidelines?			
	For non-aqueous liquids and solid dosage forms – Not later than the expiration date of the active ingredient with the earliest expiration date, or 6 months after the date the product was compounded, whichever is earlier?			
	For compounds which contain non-sterile water – Not later than 14 days after the date on which the non-sterile product was compounded?			
	For water containing topical/dermal and mucosal liquid and semisolid formulations – The beyond use date is not later than 30 days after the date on which the non-sterile product was compounded?			
	For compounds other than the above items – Not later than the intended duration of therapy or 30 days after the date the product was compounded, whichever is earlier.			

Designated Area for Non-Sterile Compounding				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67033 USP 795	There is a designated area for compounding non-sterile products?			
	Compounding areas are maintained in a clean and sanitary condition?			
	All equipment is inspected, maintained, cleaned, and validated at appropriate intervals?			
	Hot and cold water is available in the compounding area?			
	Soap or detergent is available?			
	Air driers or single service towels are available?			
	Trash is disposed of in a safe, sanitary, and timely manner?			
	The designated area is cleaned using an antiseptic cleaning method before and after any compounding occurs?			
	Equipment used to compound non-sterile drug products is cleaned immediately after compounding to prevent cross contamination?			
	If the pharmacy compounds both sterile and non-sterile drug products, none of the equipment used to compound non-sterile products is used to compound sterile products, unless the equipment is cleaned and sanitized prior to using for sterile compounding?			
	Each employee who compounds non-sterile products washed their hands with soap and water or an antimicrobial agent before and after compounding the non-sterile products?			

Storage of Non-Sterile Compounded Products				
Citation	**Question**	**Yes**	**No**	**NA**
FDA	Non-Sterile products, including, without limitation any non-sterile compounded product in excess of the amount required by a prescription or chart order, and any compounded product made in bulk quantities is stored to ensure the efficacy of the product is maintained and the product remains free of contamination?			

Non-Sterile Hazardous Drugs (HD)				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.67037	Are the components of HD stored separately from all other inventory and in such a manner and location to minimize the contamination of other drugs in and employees of the pharmacy?			
	Are components handled with caution by using appropriate gloves while distributing, receiving, stocking, inventorying, and preparing for administration and disposing of components of a HD or final compounded product?			
	Do employees involved with compounding or otherwise handling HD wear personal protective equipment, including, without limitation: gowns, face mask, eye protection, double gloves or chemotherapy gloves?			
	Is all hazardous waste disposed of in a manner that complies with any applicable state, federal, or local law or regulation?			
	Do all employees who are known to be a special risk with regard to the properties of HD are limited from exposure to those drugs?			

Notes

Your location will be inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action will be sent to the email you indicate below. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	
Pharmacist Printed Name:	
Pharmacist Signature:	
Email address for correspondence:	